

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Phillips *et al.*  
Appl No.: 10/755,545  
Filed: 1/12/04  
For: COMPOSITIONS AND METHODS FOR THE TREATMENT OF DISEASE

Confirmation No.: 1302  
Group Art Unit: 1649  
Examiner: G. Emch



Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

This is in response to the Office Action dated September 14, 2006, in which the Examiner has required restriction between Group I-XXIII. The Examiner further requires an election of a species comprising a single indication. Applicant hereby elects with traverse to prosecute the claims of Group I (Claims 1-7, 13, 21, and 22 as they relate to a pharmaceutical composition comprising follistatin). Applicants further elects with traverse to elect liver fibrosis as the indication. Applicants expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims.

I. The Examiner has restricted this application to Groups I – XVIII. Each group recites a pharmaceutical composition comprising a specific activin antagonist. The Examiner argues that each of Groups I-XVIII are distinct as they are drawn to compositions having different chemical structures and physical properties. Applicants respectfully traverse and request Group I – XVIII be examined together.

Applicants submit that independent claim 1 represents a generic linking claim. As stated in MPEP 809.03, a linking claim is identified when "an application has claims to two or more properly divisible inventions, so that a requirement to restrict the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable there from and thus linking together the invention otherwise divisible". Under linking claim practice, upon allowance of the linking claim, the restriction requirement as to the linked inventions is withdrawn and any claims depending from or otherwise including all of the limitations of the allowable linking claims will be entitled to examination in the instant application. As the claims in Groups I-XVIII are clearly linked by claim 1 that recites a pharmaceutical composition comprising an "activin antagonist," Applicants respectfully request the Examiner to acknowledge that claim 1

represent linking claims and proceed with examination under linking claim practice as outlined in MPEP 809.03.

II. Applicants respectfully request that the Examiner reconsider the restriction between Groups I and XIX and/or Groups I-XVIII and XIX. Groups I-XVIII are drawn to pharmaceutical compositions comprising activin antagonists. Group XIX is drawn to a method of preparing pharmaceutical compositions comprising the activin antagonist. On page 7, paragraph 2 of the September 14, 2006 Restriction, the Examiner provides reasons as to why the claims of Group I and XIX and/or Groups I-XVIII and XIX are distinct and therefore eligible for restriction. In responding to these arguments, Applicants is not making any admission as to the distinctness and independence of the claims in Groups I and XIX and/or I-XVIII and XIX. The arguments that follow are intended only to demonstrate the Office has failed to provide sufficient evidence to establish that the claims are distinct and independent, and therefore, absence additional evidence, the restriction between the groups should be withdrawn.

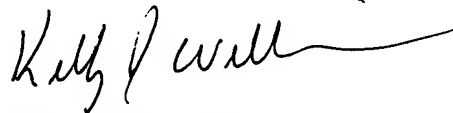
The Examiner's reasoning is not well founded. The Examiner argues that the claims in Group XIX (drawn to a method of making a pharmaceutical composition comprising an activin antagonist) can be "used to produce a plurality of activin antagonists that are not recited by the instant claims [Groups I or Group I-XVIII]" (page 7, lines 12-14 of the September 14, 2006 Restriction Requirement). However, contrary to this assertion, claim 1 is a generic linking claim that recites a pharmaceutical composition comprising an *activin antagonist*, while the claims of Group XIX recite method of making an *activin antagonist*. It therefore is unclear what "plurality of activin antagonist are not recited in the claims of Group I. The Examiner has failed to establish that the claims of Groups I and XIX and/or Groups I-XVIII and XIX are distinct. The Examiner is respectfully requested to reconsider this restriction and in view of pending generic linking claim 1, withdraw the restriction to the methods of making the composition as recited in the claims of Group XIX.

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

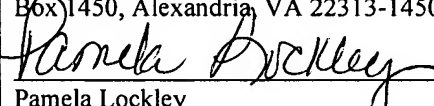
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Amdt. dated 03/09/2007  
Reply to Restriction Requirement of September 14, 2006

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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Patent Agent  
Registration No. 47,179

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| <p><b>Customer No. 00826</b><br/><b>ALSTON &amp; BIRD LLP</b><br/>Bank of America Plaza<br/>101 South Tryon Street, Suite 4000<br/>Charlotte, NC 28280-4000<br/>Tel Raleigh Office (919) 862-2200<br/>Fax Raleigh Office (919) 862-2260</p> | <p>"Express Mail" mailing label number EV913518955US<br/>Date of Deposit March 9, 2007</p> <p>I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450</p>  <p>Pamela Lockley</p> |
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